

Submitter : Mr. Samuel Coletta

Date: 02/08/2007

Organization : Avenue Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

The continued loss of revenue from inequitable reimbursements on medicare part d prescriptions and the continued under reimbursement proposed by GAO.

GENERAL

GENERAL

How about working to correct the take-it -or leave-it contracts that the PBM's force and that are protected by antitrust laws.

Provisions of the Proposed

Regulations

Provisions of the Proposed Regulations

Studies performed by Grant Thornton, LLP, used data from more than 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. The study showed that the national average cost of dispensing is \$10.50 per prescription. It also will say costs vary significantly from state to state, ranging from an average of \$8.50 per prescription in Rhode Island to \$13.08 in California.

Submitter :

Date: 02/08/2007

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

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Tell CMS the following:

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what the pharmacy actually pays for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.

A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

Submitter :

Date: 02/08/2007

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Submitter : RUTH LIGHT
 Organization : RUTH LIGHT
 Category : Other Health Care Professional

Date: 02/08/2007

Issue Areas/Comments

Collection of Information Requirements

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Submitter : Sara Hermler
Organization : Sara Hermler
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

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Submitter : Mimi Hart
Organization : Hart Pharmacy
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

GENERAL

GENERAL

I am an independent pharmacy owner. Many of my Medicaid patients are mentally ill and require that I deliver their medication to their homes in medisets - neither service for which I get paid. If I cannot even get paid what the drugs cost me, I cannot continue to provide these services and many of these patients who are currently in group or supervised homes will have to be institutionalized. I know my position is not unique and I ask that you consider what other repercussions- both monetary and emotional may come from this decision. Thank you

Submitter : Mr. Dan Stange
Organization : Health Alliance of Greater Cincinnati
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

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Submitter :

Date: 02/08/2007

Organization : Georgia Department of Community Health

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-272-Attach-1.DOC

**Georgia Department of Community Health
Comments to CMS-2238-P
Medicaid Program: Prescription Drugs**

Provisions of the Proposed Regulation

Definition of Multisource Drugs

The revised definition of multiple source drugs requiring at least one other covered outpatient drug which is pharmaceutically and therapeutically equivalent and is available in the U.S. market place is a very positive change.

Prompt Pay Discounts

The customary prompt pay discounts extended to wholesalers should be included in the AMP calculation defined in Section 6001(c). The inclusion of these discounts in the determination of the AMP price is critical to obtain a more accurate price. The challenge with the inclusion of these discounts is the timing of the information and its availability for the inclusion at the time the AMP price must be reported to CMS. The application of historical trending should be allowed, but it should undergo close scrutiny/auditing by CMS.

Mail Order and Retail Class of Trade Definition

Mail order pharmacies should be excluded from the retail class of trade definition for purposes of calculation of AMP. The purchasing power of mail order pharmacies and package sizes utilized in mail order pharmacy practice could greatly skew the reported price and the subsequent FUL. Additionally, inclusion of mail order pharmacy in the retail class of trade would further prevent Medicaid agencies from being able to use AMP pricing as a method of pharmacy provider reimbursement. Few Medicaid agencies utilize mail order as an avenue of dispensing medications to their populations. Hence, inclusion of an unobtainable price in the calculation of AMP whose purpose would be for use by Medicaid agencies is not appropriate.

Exclusion of PBM Prices

The average manufacturer price calculation should exclude PBMs who are acting as wholesalers or mail order pharmacies. Additionally, PBM rebates, discounts, as well as service or administrative fees charged by PBMs to manufacturers should not be included in the AMP calculation. AMP should reflect the average price paid by retail pharmacies or wholesalers for drugs distributed to the retail pharmacy class of trade. Retail pharmacies do not benefit from any of the PBM discounts or rebates mentioned above. Therefore, these factors should be excluded from the AMP calculation. However, should CMS decide to include mail order pharmacies in its definition of "retail class of trade," then PBM's acting as wholesalers and or mail order pharmacies would by default need to have their purchase discounts included in the calculation of AMP. Again, CMS is highly

discouraged from including mail order pharmacies (whether associated with a PBM or not) in the definition of retail class of trade.

While the exclusion of PBM rebates and discounts would result in higher AMP prices and impact manufacturers' drug rebate liability, it would also create a price that is more realistic of the average manufacturer price to pharmacies and wholesalers. This makes the AMP more appropriate as it gets included in the FUL pricing as well as making options for pharmacy reimbursement based on AMP more feasible.

Purpose of AMP

AMP now has two primary purposes. One purpose is the basis for which Medicaid rebates are calculated. The other purpose is a component in the calculation of the FUL prices. CMS states that "AMP should be calculated to reflect the net drug price recognized by the manufacturer, inclusive of any price adjustments or discounts provided directly or indirectly by the manufacturer." The DRA also changes the basis of the FUL price calculations to 250% of AMP. Putting these pieces together, Medicaid agencies must recognize that AMP is artificially low and reflects discounts to which retail pharmacies are not privy. Neither is Medicaid privy to the extent of these discounts. The difficulty is that Medicaid must somehow estimate these "price adjustments and discounts" and compensate for these factors when reimbursing pharmacy providers. AMP should not include discounts and other price adjustments not readily available to the retail pharmacy class of trade.

Estimate of Discounts

To make AMP meaningful, the use of rolling average estimates of all lagged discounts given by manufacturers to retail pharmacy class of trade purchasers should be allowed in the determination of AMP prices. Due to the potential fluctuation of these prices and the negative impact on accuracy of the FUL pricing and any other state-defined use of AMP as a reimbursement strategy, these estimates must be allowed. The use of a 12 month rolling average estimate of all lagged discounts to drug purchasers should be applied to both monthly and quarterly reported AMPs.

FUL Inclusion and Determination

The revision to the criteria for FUL inclusion from the presence of three therapeutically and pharmaceutically equivalent multiple source drugs to two such drugs is very positive. CMS should incorporate this methodology for purposes of establishing FULs for multiple source drugs.

FUL calculations should include customary prompt pay discounts extended to retail pharmacy drug purchasers. The method proposed to utilize the least costly therapeutic equivalent identified at the NDC-9 level is acceptable given the prudent measure of checking to make sure the AMP is not less than X percent of the next highest AMP for that drug. The appropriateness of the 30% proposed is not known at this point, and its rationale is not readily apparent from the document.

Submitter : Ms. Sherri Heiman

Date: 02/08/2007

Organization : Ms. Sherri Heiman

Category : Individual

Issue Areas/Comments

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Submitter : Mr. Jeff Lurey
Organization : Georgia Pharmacy Association
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

GENERAL

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This is a terrible Rule. If this Rule is implemented unchanged, it will be devastating to community pharmacy and the patients these pharmacies serve. Reimbursement rates to community pharmacies are already at rock-bottom. To further decrease these rates, especially in the area of generic drugs, would force many small independent pharmacies out of business. In many rural areas, small independent pharmacies are the only source of healthcare in the community. It makes no sense to drive these businesses out of existence. Additionally, to decrease the reimbursements on generics makes even less sense. Generics offer the only real chance to save money on prescriptions and this rule would act as a deterrent for pharmacies to switch to generics. If anything, incentives to increase generic utilization should be promoted, not the opposite as this rule does. We should be adopting rules that encourage the use of generics by offering additional incentives and we should also be encouraging pharmacists through incentives to provide medication therapy management (MTM) to their patients.

Submitter : PENNY RUNYON
Organization : PENNY RUNYON
Category : Other Health Care Professional

Date: 02/08/2007

Issue Areas/Comments

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Provisions of the Proposed Regulations

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Submitter : Mr. KEN WARMAN

Date: 02/08/2007

Organization : WARMAN'S PRESCRIPTION SERVICE

Category : Pharmacist

Issue Areas/Comments

GENERAL

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I am an independent pharmacy owner (for 20 yrs) and I am baffled as to why the federal governmental agencies all hate pharmacists. The proposal to pay at AMP is ludicrous- I will lose money on every generic Rx that I fill. Why are pharmacists not allowed to make a profit any longer? Why don't we base your salaries on the GMP and inflation rates from 20 years ago? That seems a fair as basing our reimbursement on something that we can't achieve. We are the ones on the "front lines" helping patients wade thru all of the Part D and managed care messes, and we get rewarded for that by cutting our reimbursements. Get a clue!!

Submitter : Ms. Rebecca Vierling
Organization : University of Cincinnati College of Pharmacy
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

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Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect. This is a serious issue that can hurt Medicaid recipients and pharmacies. Thank you for your time.

Submitter : Mrs. Julie Salomone

Date: 02/08/2007

Organization : Klein's Community Health Center Pharmacy

Category : Pharmacist

Issue Areas/Comments

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Submitter : Ms. ANITA DAVIS
Organization : KLEINS PHARMACY
Category : Other Technician

Date: 02/08/2007

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Submitter : Dr. armand derousseau
Organization : medical city dallas hospital
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

Background

Background

The specific NDC number of a stocked drug changes frequently throughout the year based on prices, back-orders, availability, and contract changes. When a pharmacist enters a medication order, they don't know what brand is presently on hand. To build all the possible NDC options into our computer systems for selection of the one on hand would bog down order entry efficiency and lead to increasing medication errors.

Collection of Information

Requirements

Collection of Information Requirements

NDC number information is unknown at the time of order entry.
A manual look up would greatly decrease efficiency.
Our systems don't allow for the downloading of this information as items are billed.

GENERAL

GENERAL

Not feasible from the vantage point of available labor.
Not economically feasible.
Will create non-compliance and inaccuracy if these obstacles are ignored.
Will cost more to implement than will be saved through refunds.

Provisions of the Proposed

Regulations

Provisions of the Proposed Regulations

Will require massive data base building.
Will still not bring identity of the available drug to the pharmacist at time of order entry.
Will slow down all processes.
Don't have capability to transmit NDC even if we knew the NDC.

Response to Comments

Response to Comments

Not feasible from the vantage point of available labor.
Not economically feasible.
Will create non-compliance and inaccuracy if these obstacles are ignored.
Will cost more to implement than will be saved.

Submitter : Mr. Eric Schmitz
Organization : Ohio Pharmacists Association
Category : Pharmacist

Date: 02/08/2007

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Submitter :

Date: 02/08/2007

Organization :

Category : Academic

Issue Areas/Comments

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Submitter : Mr. JEFFREY LIGHT
Organization : KLEINS MEDICAL EQUIPMENT
Category : Health Care Provider/Association

Date: 02/08/2007

Issue Areas/Comments

Regulatory Impact Analysis

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Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

Submitter : Miss. Michelle Chaffins

Date: 02/08/2007

Organization : OPA/ CMS

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.

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GENERAL

GENERAL

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect. We need to keep the market fair and profitable for all types of business.

Response to Comments

Response to Comments

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

Submitter : Mrs. Cynthia Dapore
Organization : Mrs. Cynthia Dapore
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

Background

Background

If the Government Accountability Office is correct in predicting that Community Pharmacies will lose 36% on each prescription filled, I am definitely against this bill. I work for an independent Pharmacy which strives to give customer service by giving the appropriate amount of time to each individual customer. You can expect us to stay in business if our reimbursement is below our cost. Please don't support this docket.

Thank you for your consideration.

Cindy Dapore, Rph

GENERAL

GENERAL

I'm sorry. I must have filled in the wrong box. I just want it to be known that this docket would hurt a lot of pharmacies. I work for an independent which strives to give customer service and only provides items related to the medical field. We would not have any means to recoup our losses if the insurance payment was less than cost.

Again thank you for your consideration and please do NOT support this docket

Submitter : Miss. Nicole Mathers
Organization : The Ohio State University College of Pharmacy
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.

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Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

If you have any questions, please contact OPA.

Submitter : Mr. Dan Knight
Organization : University of Cincinnati
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

GENERAL

GENERAL

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Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

Sincerely,

Dan Knight, Pharm D Candidate

Submitter : Larry Windmoeller
Organization : U of Missouri Health Care Hosptial & Clinics
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

GENERAL

GENERAL

I am writing to express my concern regarding the issue of providing a NDC number on a billing submission per the December 22, 2006 published proposal. The impact on such an issue is itself staggering. Health care organizations are under great, great work volume now and to add a "paperwork" process is unrealistic and not justifiable. With continued process of having multiple generic medications each with separate NDC numbers of the same medication makes this process overwhelmingly burdensome. I request this proposal not be implemented.

Submitter :

Date: 02/08/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

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Submitter : Jonathan Nance

Date: 02/08/2007

Organization : OPA

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

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If you have any questions, please contact OPA.

Submitter : terrell mundhenk
Organization : terrell mundhenk
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

Response to Comments

Response to Comments

I work in the small town of West Alexandria, ohio. Your proposed changes to AMP will drive my pharmacy out of business. The US government seems to be only interested in cutting budgets and fighting wars. It passes legislation to create more work like HIPPA and methamphetamine laws which increase costs. I do not understand what you are thinking. maybe we should just nationalize all of health care!!!

Submitter : Mr. Rod Tobias
Organization : Mr. Rod Tobias
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

GENERAL

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Submitter : Ms.
Organization : Ms.
Category : Individual

Date: 02/08/2007

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

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Submitter :

Date: 02/08/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

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Submitter : Ms. MARTIN MULLANEY
Organization : MULLANEY MEDICAL INC
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

Background

Background

I have been in Pharmacy for 45 years and have not seen any AVERAGE pricing reflect any TRUE price. So what do you do but cut the FEES. Pharmacy has not had any fee increase in decades. The so called AVERAGE cost to dispense a prescription is in excess of TEN DOLLARS. So if you want to use a true lower cost for the product then you also must use a true average dispensing fee, OK? You can NOT expect pharmacy to eat the cost and the fee while you get pay raises!!

GENERAL

GENERAL

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Regulatory Impact Analysis

Regulatory Impact Analysis

Submitter : Mr. DAVID MAURY

Date: 02/08/2007

Organization : griffin pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

OUR 3 PHARMACIES EMPLOY 5 FULL TIME PHARMACISTS AND 28 FULL TIME EMPLOYEES. "AMP" PLUS WHATEVER THREATENS TO CRIPPLE OUR STORES TO THE POINT OF CLOSURE. I REQUEST THAT YOU IMMEDIATELY STOP SQUEEZING THE PHARMACIES AND TAKE AN HONEST LOOK AT THE "PBM" PRACTICES THAT CONSTANTLY DECIEVE AND OVERCHARGE EMPLOYERS AND GOVERNMENT. THIS HAS GONE FAR ENOUGH IT TIME TO STOP NOW !!!!!!!!!!!!!!!

Submitter :

Date: 02/08/2007

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

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Submitter : Mr. THOMAS ARMENTROUT
Organization : PATIENT CARE PHARMACY
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

Background

Background

I'm a community pharmacist in Fairfield Ohio that provides retail pharmacy services to patients in which we also service some Medicaid patients. We have been an established business since 1980 and I have been a pharmacist since 1975

Collection of Information Requirements

Collection of Information Requirements

AMP needs to be defined so that the community pharmacist can continue to serve Medicaid patients and that it will be for a fair cost assessment of the actual cost that the retail pharmacy pays for the drugs that we provide to Medicaid patients (as well as the dispensing fee or markup must be adequate to continue to stay in business)

Regulatory Impact Analysis

Regulatory Impact Analysis

Please keep in mind the economic impact and the need for Medicaid patients to have access to pharmaceutical services in which requires a fair assessment of what really is AMP when it comes to the retail pharmacy in buying drugs to provide for their patients.

Submitter : Mr. Akram Hussein

Date: 02/08/2007

Organization : ASP

Category : Individual

Issue Areas/Comments

Collection of Information Requirements

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Submitter : Mr. Darren Mertz
Organization : Fred Meyer Stores/ Western Region Division, Kroger
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

Background

Background

I am a pharmacist and pharmacy manager of Fred Meyer #615 at 6305 Bridgeport Way, University Place, WA 98467. I am responsible for the day to day operations of this pharmacy. I annually review how much it costs our location to fill a prescription beyond the cost of medication based on wages, benefits, insurance, taxes, utilities, rent etc. I feel we run an efficient pharmacy.

Collection of Information Requirements

Collection of Information Requirements

I have become aware of efforts by CMS to recalculate how it reimburses pharamcists dispensing fees through my national pharmacy organization, APhA. A \$4.00 dispensing fee is not a realistic number. \$4.00 does not adequately reimburse my company for our efforts in the pharmacy.

GENERAL

GENERAL

I hope that my input regarding a real world cost per prescription will have an impact on your decision for service reimbursement rates.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

As I wrote earlier, I annually review our 'cost per perscription' so we can accurately implement our competative price match policy. It is currently approximately \$12.00 per prescription. We are a moderate volume pharmacy and we work efficiently.

Response to Comments

Response to Comments

If CMS goes forward with it's proposed \$4.00 dispensing fee, it would be necessary to fill more prescriptions with less resources (people).

Submitter : Molly Gates
Organization : University of Findlay School of Pharmacy
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

GENERAL

GENERAL

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Submitter : Miss. Erin Shupert
Organization : Miss. Erin Shupert
Category : Pharmacist

Date: 02/08/2007

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator Leslie Norwalk,

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Sincerely,
Erin Shupert, PharmD

Submitter : Ms. george varughese
Organization : CVS/Pharmacy
Category : Individual

Date: 02/08/2007

Issue Areas/Comments

GENERAL

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Submitter : Mr. Joseph Sabino
Organization : Pure Service Pharmacy
Category : Pharmacist

Date: 02/09/2007

Issue Areas/Comments

GENERAL

GENERAL

I operate an institutional pharmacy which provides pharmacy services to patients in long term care facilities in Ohio. The impact of lowering the drug cost component would be devastating to the pharmacies in this country. They are already struggling under the preseny arrangements. The AMP pricing that I have seen appears to take rebates to PBM's, hospitals, and large mail order pharmacies in to account. These are not available to even large chain operations let alone the smaller independent pharmacies. The AMP would lead to reimbursemwnt below costs and close most pharmacies in the country. The assertion that pharmacies would seek wholesale sources who would provide pharmaceuticals at these price levels is ludicrous. Implementation of this plan will negatively impact the sick and elderly by reducing availability of pharmacy services. If the government is serious about reducing drug costs, it should impose price controls on the pharmaceutical manufacturers and eliminate the unnecessaary and extravagant costs of promoting and advertising brand name pharmaceuticals and pay providers fairly.

Submitter : Mrs. Kara Haven
Organization : Mrs. Kara Haven
Category : Individual

Date: 02/09/2007

Issue Areas/Comments

Background

Background

Educator

GENERAL

GENERAL

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Submitter : Mrs. Mary Parsons

Date: 02/09/2007

Organization : Mrs. Mary Parsons

Category : Pharmacist

Issue Areas/Comments

GENERAL

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Submitter : Mr. Tim Bradner

Date: 02/09/2007

Organization : Rite Aid

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator Leslie Norwalk,

The proposed AMP definition under CMS-2238-P Prescription Drugs will

cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away. A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs. Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to

cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more. Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect. Thank you for your time.

Sincerely,

Tim Bradner

ONU Pharm.D. Candidate 2007

Submitter : zev zylberberg
Organization : Future Pharmacy
Category : Long-term Care

Date: 02/09/2007

Issue Areas/Comments

Background

Background

We are a long term care pharmacy provider. We supply medications to people in nursing homes, homes for adults, assisted living facilities and group homes. To help these frail adults we blister package the medications. Medication Administration Reports are generated to chart that the medication is taken properly. Delivery multiple times per day and holidays to ensure the doctor's orders are done right away.

GENERAL

GENERAL

A reduction in the reimbursement for generic drugs would eliminate the only area of profitability left for pharmacy. The Brand name drugs cost alot to the pharmacy and the reimbursement is low. The difference in price between the actual cost of the drug anp the AWP is the only way cover the increased cost of a Pharmacist.(There is a severe shortage of Pharmacists)Employee Pharmacists today make over \$ 100,000 per year. The result of this loss of income will be the inability to have sufficient pharmacists to cover the health care needs of this country

Submitter : Dr. David Kohll
Organization : Kohll's Pharmacy and Homecare
Category : Pharmacist

Date: 02/09/2007

Issue Areas/Comments

Background

Background

I am the owner of 8 retail pharmacies and healthcare centers. These are my thoughts regarding the change in generic drug reimbursement.

GENERAL

GENERAL

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mr. JOSELITO DELOSSANTOS
Organization : GANANDA PHARMACY
Category : Pharmacist

Date: 02/09/2007

Issue Areas/Comments

Background

Background

INDEPENDENT OWNER OF A BRAND NEW PHARMACY WISHING TO ACCEPT MEDICAID CLIENTS.

Collection of Information Requirements

Collection of Information Requirements

I DO NOT KNOW WHY PRICES SHOULD BE ADJUSTED BY WE HAVE BEEN CUT QUITE A FEW TIMES ALREADY. I BELIEVE CMS SHOULD LEAVE PRICING AS THEY ARE NOW.

GENERAL

GENERAL

PLEASE BE ADVISED THAT WE HAVE BEEN DRAMATICALLY AFFECTED BY CUTS ALREADY. IF THIS PRICE ADJUSTMENT IS ABLE TO BE IMPLEMENTED I ASSURE YOU THERE WILL BE MANY PHARMACIES THAT WILL CLOSE AND MANY OTHER PHARMACIES THAT WILL NOT ACCEPT MEDICAID PRESCRIPTIONS. THIS WILL EVENTUALLY DECREASE THE QUALITY OF CARE OF MEDICAID CLIENTS AND CAUSE A MAJOR PROBLEM WITH PHARMACIES THAT WILL BE ABLE TO HANDLE THEM. I ASSURE YOU TO LOOK ELSEWHERE FOR MONETARY CUTS.

Submitter : Mr. marcus wilson
Organization : Carthage Pharmacy Services, Inc.
Category : Pharmacist

Date: 02/09/2007

Issue Areas/Comments

GENERAL

GENERAL

The Centers for Medicare and Medicaid Services (CMS) should not make Average Manufacturers Price (AMP) data public until a final regulatory definition of AMP is released. This definition should reflect the prices at which traditional retail pharmacies purchase medications. CMS indicates that it will start putting these data on a public website this spring. However, release of flawed AMP data could adversely affect community retail pharmacies if used for reimbursement purposes. CMS has already delayed release of these data, and we urge that release of these data be delayed again.

CMS proposed regulatory definition of AMP is problematic because it would result in AMP values that would not reflect the prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional community retail pharmacies should be included in the AMP definition. This is what the law requires.

Mail order pharmacy and nursing home pharmacy sales should be excluded because these are not traditional retail pharmacies. Pharmacies do not have access to the special prices offered to these classes of trade.

In addition, manufacturers should not be allowed to deduct rebates and discounts paid to PBMs when calculating the AMP. Retail pharmacies do not benefit from these rebates and discounts, so the resulting AMP would be lower than the prices paid by retail pharmacies for medications. This proposed definition needs to be significantly modified.

" Delay New Generic Rates that Would Significantly Underpay Pharmacies: The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by \$8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

" Require that States Increase Pharmacy Dispensing Fees: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Submitter : Mrs. Diane Gulas

Date: 02/09/2007

Organization : Mrs. Diane Gulas

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.

A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

Submitter : Mr. Scott Davis
Organization : Memorial Healthcare System
Category : Hospital

Date: 02/09/2007

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-2238-P-313-Attach-1.DOC

CMS-2238-P-313-Attach-2.DOC

Memorial Healthcare System

MEMORIAL REGIONAL HOSPITAL • JOE DIMAGGIO ♥ CHILDREN'S HOSPITAL
MEMORIAL HOSPITAL WEST • MEMORIAL HOSPITAL MIRAMAR • MEMORIAL HOSPITAL PEMBROKE

February 9, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, Maryland 21244-8015

VIA ELECTRONIC SUBMISSION

**Re: CMS-2238-P; Medicaid Program; Prescription Drugs; 71 FR 77174;
December 22, 2006; Proposed Rule**

Dear Ms. Norwalk:

Thank you for this opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rules regarding implementation of provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs and related Medicaid rebate policies.

Memorial Healthcare System (MHS) is a multi-hospital, governmental healthcare organization located in South Florida. We are comprised of four hospitals, a freestanding nursing home, and a number of outpatient clinics and health services. For the year ended April 30, 2006, we admitted almost 75,000 patients and furnished over 630,000 outpatient visits and more than 250,000 emergency room visits. MHS is the safety-net provider of healthcare services for our market area, furnishing substantially all of the hospital and related health care services to the uninsured and underinsured population of southern Broward County, Florida.

All of our hospitals are "covered entities" as defined by section 340B of the Public Health Service Act, and we currently purchase over \$16 million of drugs annually under this program for use in our hospital outpatient departments, in our qualified hospital-based clinics, and as take-home medications for our indigent patients. Without our participation in the 340B program, our capacity to adequately serve these patients would be sharply reduced.

Our concerns with the proposed rule are detailed in the attachment to this letter. In short, they are:

- the administrative and financial burden of capturing and reporting NDC codes for drugs dispensed in our facilities;
- technical and operational issues, such as rules that could cause States to impose new rebate obligations on drugs that should be exempt from State rebates; and,

Detailed Comments on Proposed Rule on Prescription Drugs

Regulatory Impact Analysis

Under separate cover (copy attached) we are submitting comments to the CMS Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development (SORA), as well as to the Office of Information and Regulatory Affairs of the Office of Management and Budget (OIRA) regarding the calculated cost of compliance with this proposed rule.

The CMS estimate of 15 seconds per claim clearly underestimates the full cost of compliance and barely covers the time required to simply transcribe the NDC codes on those bills. It includes nothing of the cost of revising current billing systems to capture and retain NDC information, update the NDC information as codes change each calendar quarter, or to identify for each drug dispensed, the actual NDC code for that particular dose.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires the adoption of standard transaction code sets as part of the administrative simplification of claims processing. The original proposal by CMS at that time (August 17, 2000) was to adopt NDC codes as the standard code set for all pharmacy items. Response to this rule indicated an average cost per hospital of more than \$200,000 just to implement the change. Additional costs would be expected on an ongoing basis to maintain those systems and operate them.

In response to these comments, CMS issued revised final regulations on February 20, 2003, which eliminated the requirement that NDC codes be used. While this revision still permits them as an option (such as for retail pharmacies), CMS recognized the lack of benefit to offset the cost of this conversion in hospitals.

At a cost of just \$200,000 per hospital, the total cost of implementation would reach almost \$1.3 billion. The Regulatory Impact Analysis prepared by CMS indicates State and federal savings over 5 years of only \$179 million related to the implementation of section 6002 of the DRA. This clearly demonstrates that the cost of implementation far outweighs any benefits to be achieved.

In addition, we believe that the cost of maintaining systems using NDC codes would be even higher than the original \$200,000 estimate because of enhancements to drug dispensing and administration systems that would increase the amount of time spent on each drug dispense. Details are included in our attached comments to SORA and OIRA.

FFP: Conditions Relating to Physician-Administered Drugs

Proposed section 447.520 of these rules would compel States to require providers to submit all bills for drugs using NDC codes. Although the DRA only requires submission of data on single-source drugs and the top 20 multiple-source drugs, CMS recognizes correctly that providers and States would need to adopt a single billing system for all claims, rather than one for DRA-

specified drugs and a different system for all others. Therefore, the requirement for reporting effectively covers all billed drugs.

The requirement that hospitals provide NDC codes for each drug is not simply burdensome on hospitals, it may well be technically impossible to accomplish with accuracy without extraordinary efforts and cost.

Without repeating their comments, I would first refer to the concerns expressed by the National Uniform Billing Committee in their letter to former Secretary Donna Shalala (September 22, 2000), comments sent to former Secretary Tommy Thompson by the National Committee on Vital and Health Statistics (February 22, 2001), and by the American Hospital Association (July 1, 2002).

Unit Counts Do Not Match

National Drug Codes are 11-digit identifiers that specify the manufacturer, drug, and package size. Even for single-source drugs, there are generally multiple package sizes available. For multiple-source drugs, especially those that are commonly dispensed, the number of possible NDC codes is enormous. These codes indicate the package size *purchased*, not the package size *dispensed*. For example, NDC #55513-0057-04 represents four vials of 25mcg of Aranesp. If a dose of 25mcg were administered, reporting this NDC code would indicate 100mcg (4 x 25mcg). Currently, this dose of this drug is reported using HCPCS code J0881, 1mcg x 25 units. The technical requirements for converting units are overwhelming, and could lead States to seek rebates on erroneously counted units dispensed.

Business Process Redesign Would Be Required

The state of pharmacy technology today is such that most hospitals of any size utilize drug-dispensing machines located throughout the hospital for timely, controlled dispensing of prescribed medications. These machines are linked to pharmacy-controlled ordering systems that enable professional staff in the hospital to withdraw only the medications prescribed for a specific patient and only in the doses prescribed. Each medication is stored in a unique slot in the machine, which are filled/refilled by pharmacy staff.

In order for those machines to operate properly, medicines must be packaged in unit-dose quantities. The difference in unit-dose quantities and NDC package quantities is noted above. In addition, though, these drug-dispensing machines are used to monitor and control inventory levels. Unit dose packages used to stock these machines may be made up from multiple NDC packages, resulting in a mix of NDCs in a single machine slot.

When a nurse removes a dose of medication from a dispensing machine, that machine communicates to the billing system based on which machine slot was accessed, not based on which individual dose was removed from that slot.

If dose-specific NDC codes are required for billing, then the entire existing process would have to be redesigned. None of the options for redesign are favorable:

- Limit any one slot to only one NDC code. There is limited space available in these machines. Each machine is also very expensive, and takes up space in the hospital. The option of adding more machines to enable the use of multiple NDC codes is not physically possible.
- Purchase only one NDC code for any given drug. This would cause multiple problems. Costs would increase because competing NDC codes would not be accessed when their prices are lower. Shortages of a drug in a particular package size could cause outages in the hospital, or would require the hospital to reprogram all its machines on a regular basis to accommodate NDC changes.
- Disconnect the dispensing machines from the billing system and bill based on the unit-dose package. This would require implementing a manual billing process for all drugs, result in increased labor costs for every drug administered, and likely result in lost charges for hospitals because of the burden of capturing manual data.

These options do not even begin to address the complexities associated with NDC-specific billing for drug compounds that are mixed in the pharmacy, and which are currently billed using a single charge code in the hospital's billing system. Unbundling those compounds for billing would require untold additional staff time, and further redesign of billing systems.

Medicare Billing Requirements are Different

The proposed rule sets forth billing requirements for Medicaid programs using NDC codes. However, the Medicare program requires the use of HCPCS codes, with different units of measure. These two transaction code sets are not readily compatible. Translation can be made from NDC to HCPCS (where a HCPCS code applies), but a single HCPCS code may represent many NDC codes. Hospitals would still have to maintain two separate billing processes that are payer-specific. This is an undue burden on hospitals.

Covered Entities Should Retain the Benefit of 340B Pricing

When disproportionate share hospitals were added to the list of "covered entities" under section 340B of the Public Health Service Act, it was clearly the intent of Congress that these providers be enabled to benefit from the lower prices available for drugs in support of their demonstrated safety-net missions.

Existing law exempts from Medicaid rebates those drugs purchased by covered entities, so that manufacturers are not subjected to a "double rebate" related to those drugs.

The ability to bill the Medicaid program directly as we would any other payer is a vital part of our participation in the 340B program. Since Medicaid rates are based on cost, and cost savings we obtain are realized by the State in their payments for services furnished. Yet we are able to maintain a single, uniform billing process for all patients.

The requirement that the State pursue all available rebates could be construed to require that they pursue those rebates *directly*. This would require us to either carve out all Medicaid drug bills (and again maintain two separate billing systems) or drop out of the 340B program.

Manufacturers also suggest that this requirement could cause them to totally discontinue 340B pricing to providers in order to prevent duplicate discounts. The related loss of savings on non-Medicaid patients would be devastating.

We would recommend that the proposed rules be clarified to require States to pursue only those rebates that are not already exempt under section 340B of the PHS Act.

Calculation of Average Manufacturer Price (AMP)

Sections 447.504 and 447.505 of the proposed regulations address the calculation of AWP and best price, which would, if finalized, have some effect on the calculation of prices available to covered entities under section 340B of the PHS Act. There is not sufficient detail provided, and no summary by CMS, of what the overall effect on best price would be of these proposed changes. We would request that CMS analyze the effect on 340B best prices of these proposed changes, and make changes to these proposed regulations that would retain the most favorable pricing for covered entities.

Use of 9-Digit NDC Codes

The rule proposes to require calculation of AMP based on categorizing drugs using their 9-digit NDC code identifier. This level of code, versus the full 11-digit code, excludes information on package sizes. As a result, the ability to publish 340B prices publicly is sacrificed. CMS's position that Congress did not intend the use of 11-digit codes is too limited a reading of the statute. It is not inconsistent with the DRA to calculate AMP based on 9-digit code groupings, but gather and report data at the 11-digit level of specificity for purposes of 340B pricing transparency.

Exclusion from Best Price of Certain Nominal Price Sales

Section 447.508 of the proposed regulations would exempt from best price calculations sales at a nominal price, defined as it has been previously defined. However, the proposed regulations would limit which nominal price sales are so excluded. The proposed regulation includes only *outpatient* sales to certain covered entities, the IHS and DVA.

We note that in the discussion of proposed section 447.505, CMS has already recognized that inpatient prices charged to hospitals in the 340B program are also exempt from best price calculations, based on section 1002(a) of the Medicare Modernization Act of 2003.

Our request is that CMS modify the language of proposed section 447.508 to also exempt those inpatient nominal price sales made to 340B hospitals.

**COST ESTIMATE
 IMPLEMENT NDC CODES FOR MEDICAID BILLING
 MEMORIAL HEALTHCARE SYSTEM
 HOLLYWOOD, FLORIDA**

Revising Carecast

Programming changes to report NDC codes \$250,000

Adding new compendium entries for each NDC code	# new entries	10,000	
	# pharmacies	9	
	Time each (minutes)	6	
	Total Minutes	540,000	
	Total Hours	9,000	
	Cost/hr (w/bene)	55	
	Total Cost		\$495,000

Revising interfaces to Pyxis and bar-code charting \$50,000

Revising OSPAK

Cost of canisters for each NDC code	Cost Each	\$67	
	Qty	10,000	
	Cost		\$670,000

Revising Pyxis

Programming changes			
Revise billing logic			\$50,000
Revise interface to Carecast			\$12,000
Build Pyxis controller for new NDC entries	# new entries	10,000	
	Time each (minutes)	3	
	# of Controllers	5	
	Total Minutes	150,000	
	Total Hours	2,500	
	Cost/hr (w/bene)	45	
	Total Cost		\$112,500

Training Pharmacy

# staff	60	
# hrs	8	
Cost/hr (w/bene)	55	
		\$26,400

Training Nursing

# staff	5,000	
# hrs	8	
Cost/hr (w/bene)	28	
		\$1,120,000

**COST ESTIMATE
 IMPLEMENT NDC CODES FOR MEDICAID BILLING
 MEMORIAL HEALTHCARE SYSTEM
 HOLLYWOOD, FLORIDA**

Revising Billing Systems

Add charge codes for each NDC code

# codes	10,000	
# pharmacies	9	
Time each (minutes)	3	
Total Minutes	270,000	
Total Hours	4,500	
Cost/hr (w/bene)	100	
Total Cost		\$450,000

Revise billing system to accommodate NDC codes \$50,000

Maintenance of Pharmacy Systems

Add staff to maintain ongoing NDC changes

# pharmacies	9	
# shifts	1	
# staff/shift	1	
Annual salary/bene	82,000	
		<u>\$738,000</u>

Total Cost \$4,023,900

Hospitals 4

Cost per Hospital (first year) \$1,005,975

Annual maintenance cost \$738,000

Per Hospital \$184,500

5-year cost per hospital \$1,743,975



MEMORIAL REGIONAL HOSPITAL • JOE DIMAGGIO • CHILDREN'S HOSPITAL
MEMORIAL HOSPITAL WEST • MEMORIAL HOSPITAL MIRAMAR • MEMORIAL HOSPITAL PEMBROKE

January 30, 2007

Melissa Musotto
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-2238-P
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Katherine Astrich, CMS Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
Attention; CMS-2238-P
Room 10235
New Executive Office Building
Washington, D.C. 20503

**Re: CMS-2238-P; Medicaid Program; Prescription Drugs; 71 FR 77174;
December 22, 2006; Proposed Rule**

Dear Ms. Musotto and Ms. Astrich:

I am writing to you on behalf of Memorial Healthcare System in regard to the above-captioned proposed rule issued by CMS. This rule would implement certain sections of the Deficit Reduction Act of 2005 (DRA). We are deeply concerned that the regulatory impact analysis prepared by CMS for this rule is significantly flawed for the component relating to reporting of physician-administered drugs. As explained further below, there is a great cost associated with converting to such reporting that far outweighs the projected benefit associated with that reporting. Fair representation of the full costs of conversion would provide good reason for CMS to withdraw this proposal and seek other means to achieve the DRA requirements.

Memorial Healthcare System (MHS) is a multi-hospital, governmental healthcare organization located in South Florida. We are comprised of four hospitals, a freestanding nursing home, and a number of outpatient clinics and health services. For the year ended April 30, 2006, we admitted almost 75,000 patients and furnished over 630,000 outpatient visits and more than 250,000 emergency room visits. MHS is the safety-net provider of healthcare services for our market area, furnishing substantially all of the

hospital and related health care services to the uninsured and underinsured population of southern Broward County, Florida.

Background

Section 447.520 of the proposed regulations implements section 6002 of the DRA, which requires, among other things, that information regarding utilization of physician-administered drugs be collected reported by States "...using National Drug Code [NDC] codes *unless the Secretary specifies that an alternative coding system should be used.*" [DRA §6002(a)(7)(C), emphasis added].

The key purpose of this section of the DRA is to help ensure that States are collecting the full rebates due for drug manufacturers under section 1927 of the Social Security Act.

The regulatory flexibility analysis presented by CMS in this notice makes two broad, problematic assumptions. First, it assumes that most Medicaid recipients who are furnished physician-administered drugs are also Medicare beneficiaries. Second, it assumes that the cost to implement this rule is limited to 15 cents per claim. These assumptions result in an annual cost of only \$344,000 nationally, compared to annual benefits from improved rebate collections of about \$36 million.

However, when these assumptions are corrected, costs to implement conversion to NDC codes and maintain ongoing changes to those codes range from \$1.3 *billion* and up.

Assumptions Required for Full Implementation

The CMS analysis apparently counts only the time required to transcribe the NDC code on a bill. What it fails to count are the costs associated with:

- Revising pharmacy order-entry, packaging, and dispensing systems to be NDC-code specific;
- Training pharmacy staff to utilize NDC codes for billing in addition to inventory control;
- Training nursing and other clinical staff to utilize new codes and revised order-entry systems;
- Maintaining ongoing changes to NDC codes, which are much more frequent than changes to HCPCS codes used today; and,
- Equipping hospitals with additional dispensing and storage tools to segregate differing NDC codes related to the same drug.

Attached to this letter are our comment letter to CMS on this proposed rule and our initial estimate of the cost to convert and maintain our system to use NDC codes instead of HCPCS codes. For our four-hospital system, the cost per hospital over 5 years exceeds \$1.7 million each.

In 2000, the Secretary issued final rules implementing standardized transaction codes to be used for healthcare transactions under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those rules required NDC codes as the standard code set for all pharmacy transactions.

Based on feedback from the healthcare industry, final regulations issued February 20, 2003 revoked that requirement. Feedback in part included a cost estimate of \$200,000 per hospital to convert to NDC codes, or over \$1.3 billion nationally. This estimate per hospital is far below our own, but the national estimate includes many hospitals smaller than ours. Yet even this low per-hospital estimate shows that the cost of implementation far outweighs CMS's estimate of benefit.

Also, CMS has estimated the Medicaid volume based on an assumption that most all Medicaid patients receiving physician-administered drugs are also Medicare patients. In such situations, for hospital-administered drugs, Medicare is the primary payer, and such drugs are not subject to Medicaid rebates.

Furthermore, a substantial portion of Medicaid recipients are under age 65 and not disabled. They include children, pregnant women, and other medically-indigent persons. The number of transactions estimated to be affected by CMS needs further reconsideration.

Finally, the estimate of benefit is also questionable.

All of our hospitals are "covered entities" as defined by section 340B of the Public Health Service Act, and we currently purchase over \$16 million of drugs annually under this program for use in our hospital outpatient departments, in our qualified hospital-based clinics, and as take-home medications for our indigent patients. The savings we achieve on these purchases are included in our annual Medicare and Medicaid cost reports, providing the basis for the State to recoup its share of those savings in our Medicaid payment rates.

If we are required to file our Medicaid bills using NDC codes so that the State may directly pursue rebates, there will be *no net savings* to the State for those drugs – the savings is already being achieved. The cost-benefit analysis for our hospitals is all cost, no benefit.

Recommendation

The regulatory flexibility analysis by CMS should be replaced with a more comprehensive, accurate analysis of both costs and benefits. Transition to NDC codes is not warranted, and the Secretary should pursue use of HCPCS codes for reporting, as permitted by the DRA section emphasized above.

Submitter : Dr. danny dang
Organization : independent pharmacy
Category : Pharmacist

Date: 02/09/2007

Issue Areas/Comments

Background

Background

I am pharmacist practicing at Congress Pharmacy, an independent entity in New York City. I completed PharmD 2004 at Long Island University, Brooklyn NY. I have dedicated all my time and knowledge to ensure and maximize my patient's health and improve their knowledge on medications and disease states. As well as interacting with health care providers to provide drug informations, treatment options as well as education and speeches to patients and health-care providers.

Collection of Information Requirements

Collection of Information Requirements

Medicaid Outpatient Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs, GAO-07-239R, December 22, 2006

GENERAL

GENERAL

With all respects to all decision makers, I believe the new proposal medicaid out patient drug reimbursement will jeopardize pharmacist professions as well healthcare system. The proposal was unfair to pharmacists and pharmacy. We are already suffering medicare part D hassles and harrassment from medicare part D plans for slow response, inadequate eligibility, coverage, prior approval information that we spend hours to resolve on our patients behalf. We did it for free. CMS was praising pharmacists' role in helping patients. Instead of rewarding or make our tasks easier, the new policy threatens to force pharmacies out of service due to severe loss on new reimbursement by this policy GAO 07-239R. No healthcare professionals are able to sustain business if they deliver health care service at a loss. As result of this policy, more pharmacies close out, more pharmacists lose jobs, and most importantly patients are not accessible to services.

All decision makers should ask yourself a very basic question before voting, if you say Yes to below questions then you go ahead and support this policy, else I strongly urge you to vote NO.

- 1.> Are you able to operate a business at a loss for each service to your patients?
- 2.> Is there a price tag to your health? Is your health is worthless?
- 3.> When was the last time you or your loved ones fill(antibiotic, asthma, diabetes,etc) prescriptions at your local pharmacies to fulfill your life threatening needs, and now you decide to vote to close those pharmacies and have your prescriptions mailed to you or going distant and crowded pharmacies to bargain your lucks?
- 4.> How would the pharmacies service would be like when baby boomers are retired? Are you denying them to our services?

I am asking you to rationalize your thinking to make a wise decision for our society. Our society increases needs for pharmacists knowledge and expertise to assist and to improve patients care. Please do not close the chapter on our pharmacist professions.

I am happy and delighted to assist you and any officials to visit my pharmacy and others to witness services and our patients needs then you will have a better information to form a wiser decision.

On behalf of all American Citizens and pharmacy staffs, I would like to thanks for your effort to address pharmacist's concerns to your colleague.

Please contact me at 718 665-6771 or email me at dannyd@congresspharmacy.com if I can help you further.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Medicaid Outpatient Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs, GAO-07-239R, December 22, 2006

Response to Comments

Response to Comments

Pharmacies close-out, pharmacy staffs will be out of job, services are limited or inaccessible to patients depending on locations, more unnecessary emergencies and hospital services, while saving money by cutting pharmacy reimbursement, the insurance, tax payers and government pays more to unnecessary medical services.

Submitter : Mrs. Julie Perkins
Organization : Batson's Drug Store
Category : Pharmacist

Date: 02/09/2007

Issue Areas/Comments

GENERAL

GENERAL

I own the only pharmacy in Elk County Kansas. I am proud that I have had the business expertise to keep my pharmacy afloat after all the changes Medicare Part D created for my rural remote pharmacy. I am writing to voice my concerns over the proposed changes to pricing and AMP. Pharmacies have already taken a HUGE brunt of the price cuts that have occurred in the healthcare field in recent years. We have cut back our overhead as much as I see is possible and I greatly fear this next round. We can't take anymore! My customers will have no other option than a pharmacy that is located an hour away from their home. The amount we will be paid to dispense a prescription does not even cover what it costs to fill a prescription. I need to be able to do more than break-even on the cost of the medication. I must also receive enough money to pay for the label, the bottle, the sack, the staple, the receipt, the ink, the electricity, the employee, the heat (or air conditioner), the insurance, the delivery expense, repairs, maintenance, taxes, telephone, sewer, trash, and my time! Do you see where any of these can be eliminated? I don't. Small pharmacies can't take anymore! It may be hard to understand when you have a chain pharmacy on every corner in the large cities, but you are severely damaging rural America! Please stop this from proceeding forward!! We are going out of business at an alarming rate. I BEG YOU, PLEASE HELP!!

Submitter : Gregory Wissel

Date: 02/09/2007

Organization : Gregory Wissel

Category : Pharmacist

Issue Areas/Comments

GENERAL

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The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.

A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

Submitter : Ms. Teresa Robinson
Organization : Ohio Northern University Student
Category : Pharmacist

Date: 02/09/2007

Issue Areas/Comments

GENERAL

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Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

Submitter : Mr. Griffith VINCENT

Date: 02/09/2007

Organization : Sterling Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I own Sterling Pharmacy, a very small pharmacy in a town of only about 2,000 people. The proposed AMP definition under CMS-2238-P Prescription drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, I may have to turn Medicaid patients away. A proper definition of AMP is the first step towards fixing this problem. I understand that the secretary of the department of health and human services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacies' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by my pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover my costs.

If underpaid on Medicaid prescriptions, I will be forced to turn Medicaid patients away, cutting access for patients. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

Grif Vincent
740-869-3784

Submitter : Mr. GREGORY DIEHL
Organization : GLEN CENTER PHARMACY
Category : Pharmacist

Date: 02/09/2007

Issue Areas/Comments

GENERAL

GENERAL

Congratulations! This proposed reimbursement schedule will complete the job that the insurance companies started and deal the final blow to independent retail pharmacy, perhaps even chain retail. It is fine to lump me in with mail-order so long as I am able to buy at the mail order rate.

I am willing to compete every day on a level playing surface. This legislation will surely push me out of my profession.

Include kick-backs that PBM's receive? How can you? I don't get those rebates.

Pricing updates - why not regulate the industry so they can only raise prices on the every 6 months on Jan 1st and July 1st and they need to provide 60 days advance notice. That way we won't be dispensing Rx's at a loss.

I encourage you to work on the margin you are asking us to.

Submitter : Mr. howard feder
 Organization : v.g.h.pharmacy inc
 Category : Pharmacist

Date: 02/09/2007

Issue Areas/Comments

Background

Background

1

OVERVIEW

CMS's Costs Savings Estimates Ignore Increased Costs

AMP-based FULs will not cover pharmacy acquisition costs for multiple-source generic medications. In their latest report, the GAO specifically finds:

The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower

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than average retail pharmacy acquisition costs for the 27 high expenditure drugs in our sample and 15 percent lower, on average, for the 27 frequently used drugs in our sample. For the 23 drugs that overlapped both categories of drugs, the estimated AMP-based FULs were, on average, 28 percent lower than the average retail pharmacy acquisition costs. In addition, we also found that the lowest AMPs for the 77 drugs in our sample varied notably from quarter to quarter. Despite this variation, when we estimated what the AMP-based FULs would have been using several quarters of historical AMP data, these estimated FULs were also, on average, lower than average retail pharmacy acquisition costs from the first quarter of 2006. -GAO-07-239R

p.4

This finding validates community pharmacy's contention that AMP is not appropriate as a baseline for reimbursement unless it is defined to reflect pharmacy acquisition cost. The application of a faulty AMP definition in calculation of the FUL will force many independent pharmacies to discontinue service to their Medicaid patients and some independents will close completely. This lack of access to timely and safe prescription drug care will lead to additional costs to state Medicaid budgets for increased doctor visits, emergency room care, hospital stays and long term care expenses. Those pharmacies that remain in the Medicaid program will face a perverse incentive to dispense more profitable, higher-cost brand name medicines, thus driving Medicaid costs even higher.

None of these serious consequences have been accounted for in the proposed rule; in fact, the proposed rule creates many of these consequences.

Conflict in the Use of AMP as a Baseline for Reimbursement and an Index for Rebates
 AMP is now to serve two distinct and contrary purposes: 1) as a baseline for pharmacy reimbursement, and 2) as an index for manufacturer rebates paid to states. AMP was never intended to serve as a baseline for reimbursement, and may not have been an effective measure for manufacturer rebates as outlined in the report Medicaid Drug Rebate Program Inadequate Oversight Raises Concerns about Rebates Paid to States (GAO-05-102).

However, if AMP is to accurately serve both purposes, CMS MUST define AMP to reflect the actual cost paid by retail pharmacy, excluding all rebates and price concessions NOT available to retail pharmacy. All rebates and price concessions are appropriately included in Best Price but should not be included in AMP.

An accurate definition of AMP and Best Price will not only lead to greater rebates to state Medicaid agencies, but will also set an accurate baseline for adequate reimbursement rates. This will encourage the use of more affordable generics, thus saving money for the entire system while promoting effective patient health care.

Collection of Information Requirements

Collection of Information Requirements

The following is a summary of NCPA's suggested comments to CMS. Specific CMS requests for comment (in bold, with page reference) are followed by an NCPA response.

Inclusion of all mail order pharmacy prices in retail pharmacy class of trade. pg. 29

29

Public Access Defines Retail Pharmacy Class of Trade

CMS is correct to exclude hospital and nursing home sales from the retail pharmacy class of trade for two reasons. First, hospital and nursing home pharmacies are extended prices not available to retail pharmacy. Second, nursing homes and hospitals are not deemed to be publicly accessible. Mail order facilities are operated almost exclusively by PBMs, and as such they meet both of these criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible. Sales to mail order facilities should not be included in AMP.

NCPA recommends retail pharmacy class of trade include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies a definition that currently encompasses some 55,000 retail pharmacy locations.

Inclusion in AMP of PBM rebates, discounts, and other price concessions for drugs provided to retail pharmacy class of trade. pg. 31-33

Inclusion in Best Price of PBM rebates, discounts and other price concessions pg. 53

Treatment of Manufacturer coupons with regard to Best Price pg. 55

Inclusion of Direct-to-Patient Sales with regard to AMP pg. 41

AMP Must Differ From Best Price

If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade.

CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE and to the Department of Veterans Affairs (VA). CMS should also exclude rebates paid to PBMs from AMP calculation: These rebates are not available to the retail pharmacy class of trade, and indeed, none of these funds are ever received by retail pharmacy; and the Retail Pharmacy Class of Trade does not have access to Direct to Patient Sale prices, and therefore these transactions should also be excluded from AMP calculation.

The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs receive manufacturer rebates off of the

4 market price of those drugs. Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive.

For states to receive a rebate benefit more closely matching the marketplace, Best Price was created as a contrasting measure to AMP. Manufacturers must pay states either a percentage of AMP or the difference between AMP and Best Price, whichever is greater. In this context, Best Price is then the most appropriate vehicle in which to include PBM rebates, discounts and other price concessions as well as Direct-to-Patient sales and manufacturer coupons.

GENERAL

GENERAL

Subject: plea for sanity in an insane world

Pharmacy Benefit Managers make so much money from the prescriptions they adjudicate that a PBM officer had enough money to fund his own multi-million dollar campaign for governor of New Jersey. There seems to be something wrong here. The feds are screaming that medicaid/medicare costs too much, then they turn it over to the pbms that are making so much money that a multi-million dollar fine can be easily handled by them. one pbm is taking over another pbm for 26 billion dollars am i wrong in thinking that the 26 billion dollars will come out of our pockets? the difference in what they charge the insurance and what they pay pharmacies to dispense the medication plus the rebates they get from the drug companies for putting thier drugs on formulary is a trade secret according to them. if they had to let us know how much they were making maybe someone would wake up and put a stop to this rape of the country. don't they see that the pbms are part of the problem not the solution.

the other major component of the problem is the drug companies themselves. they pay more for lobbying, advertising, rebates both to governments and pbms, political contributions both visible and not then they pay to research the original drug. drug price has nothing to do with the cost of the actual drug. in many cases the actual cost of the drug is so low that they can afford to give it away to people who can't afford the price that the various insurances pay for them. drug companies make more money from manipulating dosage forms and making a spectrum of combination products than they do from original research into new drugs. each new dosage form and group of combo-drugs is priced as though it was an original research product.

as long as there are no controls in place for these industries, and as long as they keep supporting the people in power(who have health insurance and retirement

plans that we pay for) we will remain in the pit we have been placed in by the very people we have trusted to get us out of this mess. this new federal initiative will be the final blow to the independant pharmacies that serve the medicaid / medicare population. the people who spend hours on the phone with the part d plans, doctors and caregivers. we can barely make ends meet now. name another profession that exists on a profit margin of less than 10%. somehow this administration thinks that the burden of high drug prices should be carried by the people making the least money from this situation. the drug companies make billions, the benefit managers have billions of dollars to take each other over, but lets take 90% of 8.4 billion from the people who make pennies and who serve the penniless.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

How PBM price concessions should be reported to CMS. pg. 33

PBM Transparency Necessary to Assess Manufacturer Rebates

PBMs are not subject to regulatory oversight, either at the federal or state levels.

Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those adjustments to the net drug prices is inappropriate. CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry. PBMs, have fought in both the national and state legislative arenas, to keep that information from review by the government and their own clients. Their contracts are not subject to audit provisions, except in some cases where the client selects an auditor that the PBM approves. Lastly, the PBM is allowed, again through lack of regulation; to self refer to its wholly owned mail order pharmacy. No other entity in the health care arena is allowed to self-refer to its own wholly owned business.

Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP. pg. 70

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly.

Use of the 11-digit NDC to calculate AMP pg 80

AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy

5

We concur with the many reasons CMS offers in support of an 11-digit NDC calculation of the FUL. CMS suggests calculating the FUL at the 11 digit NDC would offer advantages to the program, will align with State Medicaid drug payments based on package size, will allow greater transparency, and would not be significantly more difficult than calculating the FUL from the 9 digit code.

Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.

Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-digit NDC would NOT adequately cover pharmacy acquisition cost. The 11-digit NDC must be used when calculating the FUL.

Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients. pg. 110

CMS discusses impact on pharmacy:

? On independents: potential significant impact on small, independent pharmacies. pg. 101

? On all retail: \$800 million reduction in revenue in 2007; \$2-billion annually by 2011 (a small fraction of pharmacy revenues). pg. 108

? We are unable to estimate quantitatively effects on small pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. pg. 110

Impact on small pharmacies demonstrated by GAO findings

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction.

Regulatory Impact Analysis

Regulatory Impact Analysis

This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees. The impact on independent pharmacies also cannot be mitigated by an increase in state-set dispensing fees. If state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is also unlikely that states would set dispensing fees high enough to cover the average \$10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study. Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.

6
If these dispensing costs, in addition to drug acquisition costs, are not covered, pharmacies simply cannot afford to continue participation in the Medicaid program. By law, CMS cannot mandate minimum dispensing fees for the Medicaid program; however, the proposed rule must provide a comprehensive definition on Cost to Dispense for states to consider when setting Dispensing Fees.

CMS Must Employ a Complete Definition on Cost to Dispense
The Definition of Dispensing Fee does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments.

Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Most importantly, they provide an important health, safety and counseling service by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient.

Policing and Oversight Process for AMP and Best Price Must Be Included
The new proposed Dual Purpose of AMP requires that AMP be calculated and reported properly and accurately. Both the GAO and the HHS Office of Inspector General have issued reports citing historical variances in the reporting and calculation of AMP. While some of these concerns will be corrected in the new rule, CMS has not proposed nor defined a policing and oversight process for AMP and Best Price calculation, reporting and auditing.

All calculations should be independently verifiable with a substantial level of transparency to ensure accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.

Response to Comments

Response to Comments

Summary of Key Points:

- _ The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- _ Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
- _ To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by

- 7
1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
2. Excluding all mail order facilities and PBM pricing from AMP calculation: Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.
3. Reporting AMP at the 11-digit NDC level to ensure accuracy

Submitter : Phillip Sollon
Organization : Sollon Pharmacy
Category : Pharmacist

Date: 02/09/2007

Issue Areas/Comments

Background

Background

25 Years of Community based retail pharmacy.

Collection of Information Requirements

Collection of Information Requirements

Calculation of AMP

Rebates

Price changes

Costs of dispensing

GENERAL

GENERAL

I am available for more "grass roots" discussion on these topics should anyone wish to contact me.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Published readily available data

Regulatory Impact Analysis

Regulatory Impact Analysis

AMP does NOT reflect costs incurred by independent retail pharmacy.

AWP more closely is associated with true costs.

Rebates are geared to PBM's and mail-order-houses, and are not to be considered available to independent pharmacy.

Prices change daily and at the least should be updated on a weekly basis.

Documented studies show the true costs associated with dispensing.

Response to Comments

Response to Comments

Use of AMP pricing, non-conforming price-updates, and inclusion of high end rebates would be devastating to our business and put many patients at the risk of interrupted health care due to lack of availability and freedom of access to their prescription medications.

Submitter : Mr. Upendra Solanki

Date: 02/09/2007

Organization : Mr. Upendra Solanki

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The impact of this legislation will be very dramatic. It will be a negative for patients because it will limit access to care. It will also be detrimental to care in the sense that Community Pharmacy will be impacted negatively. A large number of jobs will be lost in community pharmacy and access to the elderly and disenfranchised will be limited!

Submitter : Mr. Joe Wedig
Organization : Mr. Joe Wedig
Category : Other Health Care Professional

Date: 02/09/2007

Issue Areas/Comments

GENERAL

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Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

Submitter : Mr. delane bassett
Organization : iuling discount pharmacy
Category : Pharmacist

Date: 02/09/2007

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir

I own a small pharmacy in rural central texas. If your proposed reimbursement for medicaid rx's takes affect, my store will be forced to no longer accept texas medicaid. I dread seeing the affect on these old and poor people when they no longer have their medicine . Please reconsider .

Thanks,

Delane Bassett Rph

Submitter : Dr. Wiliam Valutsky
Organization : Methodist Ambulatory Surgery Hospital
Category : Pharmacist

Date: 02/09/2007

Issue Areas/Comments

GENERAL

GENERAL

A longer time for the rule to take effect is needed. Currently there are NO software programs in place to provide NDC numbers on pt bills. It would take at least a year to develop and test a program to do what is required on this proposal.

Submitter : Mr. edward salser

Date: 02/09/2007

Organization : edwards drug co

Category : Drug Association

Issue Areas/Comments

Background

Background

i have been in retail business since 1956 and have survived be hard woprk and family devotion to service. i note that on the horizon is a plan which will effectively no longer allow service to our community or prospects for survival.if prayer would work
i will pray that some one takes stock of what is happening. dear God.

Submitter : Mr. edward salser

Date: 02/09/2007

Organization : edwards drug co

Category : Pharmacist

Issue Areas/Comments

Background

Background

I NOTE THAT AFTER SERVING THE PUBLIC SINCE THE 1950'S SHE SERVICE TO MY COMMUNITY WILL BE THREATENED AND MY BUSINESS PROBABLY WON'T SURVIVE
WON'T SOME SANITY PREVAIL. I IMPLORER SOMEONE WILL UNDERSTAND THE DAMAGE THAT WILL BE DONE TO RETAIL PHARMACY AND THE PERSONS THEY SERVE

Submitter : howard feder
 Organization : myrtle ave. pharmacy
 Category : Pharmacist

Date: 02/09/2007

Issue Areas/Comments

Background

Background

1

OVERVIEW

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2

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p.4

This finding validates community pharmacy's contention that AMP is not appropriate as a baseline for reimbursement unless it is defined to reflect pharmacy acquisition cost. The application of a faulty AMP definition in calculation of the FUL will force many independent pharmacies to discontinue service to their Medicaid patients and some independents will close completely. This lack of access to timely and safe prescription drug care will lead to additional costs to state Medicaid budgets for increased doctor visits, emergency room care, hospital stays and long term care expenses. Those pharmacies that remain in the Medicaid program will face a perverse incentive to dispense more profitable, higher-cost brand name medicines, thus driving Medicaid costs even higher.

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How PBM price concessions should be reported to CMS. pg. 33

PBM Transparency Necessary to Assess Manufacturer Rebates

PBMs are not subject to regulatory oversight, either at the federal or state levels.

Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those adjustments to the net drug prices is inappropriate. CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry.

GENERAL

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Summary of Key Points:

- _ The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- _ Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
- _ To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by

7

1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
2. Excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.
3. Reporting AMP at the 11-digit NDC level to ensure accuracy

Provisions of the Proposed Regulations

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PBMs, have fought in both the national and state legislative arenas, to keep that information from review by the government and their own clients. Their contracts are not subject to audit provisions, except in some cases where the client selects an auditor that the PBM approves. Lastly, the PBM is allowed, again through lack of regulation; to self refer to its wholly owned mail order pharmacy. No other entity in the health care arena is allowed to self-refer to its own wholly owned business.

Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP. pg. 70

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly.

Use of the 11-digit NDC to calculate AMP pg 80

AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy

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We concur with the many reasons CMS offers in support of an 11-digit NDC calculation of the FUL. CMS suggests calculating the FUL at the 11 digit NDC would offer advantages to the program, will align with State Medicaid drug payments based on package size, will allow greater transparency, and would not be significantly more difficult than calculating the FUL from the 9 digit code.

Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.

Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-digit NDC would NOT adequately cover pharmacy acquisition cost. The 11-digit NDC must be used when calculating the FUL.

Regulatory Impact Analysis

Regulatory Impact Analysis

CMS discusses impact on pharmacy:

? On independents: potential significant impact on small, independent pharmacies.

pg. 101

? On all retail: \$800 million reduction in revenue in 2007; \$2 billion annually by 2011 (a small fraction of pharmacy revenues). pg. 108

? We are unable to estimate quantitatively effects on small pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. pg. 110

Impact on small pharmacies demonstrated by GAO findings

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees.

The impact on independent pharmacies also cannot be mitigated by an increase in stateset dispensing fees. IF state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is also unlikely that states would set dispensing fees high enough to cover the average \$10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study.

Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.

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If these dispensing costs, in addition to drug acquisition costs, are not covered, pharmacies simply cannot afford to continue participation in the Medicaid program. By law, CMS cannot mandate minimum dispensing fees for the Medicaid program; however, the proposed rule must provide a comprehensive definition on Cost to Dispense for states to consider when setting Dispensing Fees.

CMS Must Employ a Complete Definition on Cost to Dispense

The Definition of Dispensing Fee does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments.

Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Most importantly, they provide an important health, safety and counseling service by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient.

Policing and Oversight Process for AMP and Best Price Must Be Included

The new proposed Dual Purpose of AMP requires that AMP be calculated and reported properly and accurately. Both the GAO and the HHS Office of Inspector General have issued reports citing historical variances in the reporting and calculation of AMP. While some of these concerns will be corrected in the new rule, CMS has not proposed nor defined a policing and oversight process for AMP and Best Price calculation, reporting and auditing.

All calculations should be independently verifiable with a substantial level of transparency to ensure accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.

Response to Comments

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Submitter : howard feder

Date: 02/09/2007

Organization : howard feder

Category : Individual

Issue Areas/Comments

Background

Background

Subject: plea for sanity in an insane world

Pharmacy Benefit Managers make so much money from the prescriptions they adjudicate that a PBM officer had enough money to fund his own multi-million dollar campaign for governor of New Jersey. There seems to be something wrong here. The feds are screaming that medicaid/medicare costs too much, then they turn it over to the pbms that are making so much money that a multi-million dollar fine can be easily handled by them. one pbm is taking over another pbm for 26 billion dollars am i wrong in thinking that the 26 billion dollars will come out of our pockets? the difference in what they charge the insurance and what they pay pharmacies to dispense the medication plus the rebates they get from the drug companies for putting their drugs on formulary is a trade secret according to them. if they had to let us know how much they were making maybe someone would wake up and put a stop to this rape of the country. don't they see that the pbms are part of the problem not the solution.

the other major component of the problem is the drug companies themselves. they pay more for lobbying, advertising, rebates both to governments and pbms, political contributions both visible and not then they pay to research the original drug. drug price has nothing to do with the cost of the actual drug. in many cases the actual cost of the drug is so low that they can afford to give it away to people who can't afford the price that the various insurances pay for them. drug companies make more money from manipulating dosage forms and making a spectrum of combination products than they do from original research into new drugs. each new dosage form and group of combo-drugs is priced as though it was an original research product.

as long as there are no controls in place for these industries, and as long as they keep supporting the people in power (who have health insurance and retirement plans that we pay for) we will remain in the pit we have been placed in by the very people we have trusted to get us out of this mess.

this new federal initiative will be the final blow to the independant pharmacies that serve the medicaid / medicare population. the people who spend hours on the phone with the part d plans, doctors and caregivers. we can barely make ends meet now. name another profession that exists on a profit margin of less than 10%. somehow this administration thinks that the burden of high drug prices should be carried by the people making the least money from this situation. the drug companies make billions, the benefit managers have billions of dollars to take each other over, but lets take 90% of 8.4 billion from the people who make pennies and who serve the penniless.